Remarks

Claims 1-3, 8-16, 30, 51-52, and 57-58 are currently pending in this matter. By way of the amendment of this date, new claim 59 has been added. Thus, claims 1-3, 8-16, 30, 51-52, and 57-59 are currently before the Examiner for consideration. Support for the newly presented claim can be found, for example, at page 61, lines 21-25 of the Specification. Applicants also respectfully request consideration of the After Final Amendment filed March 11, 2002. Applicant wishes to thank the Examiner for the courtesy of the interview extended on October 19, 2001 to discuss the outstanding rejections. It is believed that this response addresses those issues discussed during the course of the interview and is consistent with the discussion.

The subject invention provides unique and advantageous *Chlamydia trachomatis* polynucleotides, vectors, transformed host cells, DNA chips, and kits containing the aforementioned polynucleotides. Certain of the claims have been, previously, amended for the purpose of expediting the patent application process in a manner consistent with the Patent and Trademark Office Patent Business Goals (PBG), 65 Fed. Reg. 54603 (September 8, 2000), advancing prosecution, and facilitating the business interests of Applicants. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 57-58 were rejected under 35 U.S.C. § 112, first paragraph, as non-enabled by the subject specification. In order to expedite prosecution of the subject application to completion, a Declaration by Applicants' representative indicating that the clones recited in claims 57-58 have been deposited at the European Collection of Cell Cultures (Porton Down, Salisbury, Wiltshire SP4 0JG, United Kingdom) under the terms of the Budapest Treaty, and further indicating that all restrictions imposed by the depositor on the availability to the public of the deposited microorganism will be irrevocably removed upon granting of a patent was filed on March 11, 2002. A copy of this declaration accompanies this paper. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

Claims 1-3, 8-16, 30, 51-52, and 57-58 have been rejected under 35 U.S.C. § 101 as lacking patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility. The Office Action alleges that the specification fails to connect the claimed invention to any particular or specific utility and that no substantial utility has been established for the claimed subject matter. The Office Action argues that Applicants have not demonstrated that the

claimed sequences are not conserved over other closely, or distantly, related organisms and that, thus, the utility of the sequences requires further research. Applicants respectfully traverse.

Applicants submit that the claimed subject matter has patentable utility (*i.e.*, "specific", "substantial", "credible", and "well-established" utility) and meets the definitions set forth in the Office Action of April 17, 2001 at pages 2-3. Applicants reiterate, and hereby incorporate by reference, the arguments set forth in the response of July 17, 2001.

The Office Action further maintains this rejection on the grounds that Applicants have not demonstrated that the claimed sequences are conserved among different species or that the sequences are unique to *C. trachomatis*. As discussed in the interview of October 19, 2001, searches conducted by the Patent Office regarding this aspect of the rejection appear to be predicated on the possibility that use of the claimed sequences may result in "false positives" when used in hybridization assays or in PCR amplification assays. As discussed in the specification at page 87, line 23 through page 88, line 18, sequences were examined for homologies according to known methods. The sequences claimed herein did not exhibit significant homologies to other organisms (see Table I). Furthermore, searches conducted by the Patent Office do not indicate that there is a significant likelihood for the identification of "false positives" when the claimed sequences are used in hybridization or amplification assays. By way of example, the following table provides a synopsis of the sequences identified by the Patent Office, corresponding GenBank Accession numbers, and the organisms associated with each respective sequence.

SEQ ID NO:	GenBank Accession No.	Organism from which GenBank Sequence was Derived	Source
1083	X68033	*Pseudomonas sp.*	Human pathogen
1089	M74221	*Chlamydia trachomatis*	Human pathogen
1091	Z11839	*Thermotoga maritima*	Thermophilic marine bacterium
1095	T67502	*Helicobacter pylori*	Human pathogen (found in stomach and duodenum)
1096	Q54841	*Homo sapiens*	Non-bacterial source
1105	X63515	*Rattus norvegicus*	Non-bacterial source (rat)
1117	U76535	*Thermococcus barossii*	Marine hyperthermal source
1140	L35530	*Halobacterium cutirubrum*	Environmental salt ponds
1159	X59601	*Rattus norvegicus*	Non-bacterial source (rat)
1167	N70920	*Bacillus stearothermophilus*	Compost (grows at extreme temperatures)

Applicants submit that the claimed subject matter has patentable utility (*i.e.*, "specific", "substantial", "credible", and "well-established" utility) and meets the definitions set forth in the Office Action. Indeed, as the Federal Circuit has noted, even if an invention has limited utility and may only be operable in certain applications, there is no grounds for finding lack of utility. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958-59, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983); *Carpet Seaming Tape Licensing Corp. v. Best Seam, Inc.*, 694 F.2d 570, 578, 216 U.S.P.Q. 873, 880 (9th Cir. 1982). Some degree of utility is sufficient for patentability (see *E.I. du Pont de Nemours & Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 U.S.P.Q. 1, 10 [n.17] (8th Cir. 1980)) and an allegation of non-utility cannot be sustained without proof of total incapacity. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 [221 USPQ 473, 480] (Fed. Cir. 1984). It is respectfully submitted that the Office Action fails to meet its burden of proof, namely proof of total incapacity, and that, contrary to the allegations of the Office Action, the claimed inventions have utility.

As will be noted, only three of the sources for the homologous sequences are derived from human pathogens. One of which is *C. trachomatis,* which would not provide a false positive result. Seven of the sources from which the homologous sequences are derived are extremophiles (*e.g.*, organisms that are not human pathogens) or are derived from non-bacterial sources (*i.e.*, humans or rats). Thus, at least eight of the sequences would not be expected to give rise to "false positive" results discussed during the course of the interview.

While the possibility exists that SEQ ID NO:1083 or 1095 may give rise to a "false positive", it is respectfully submitted that this does not raise an issue related to the utility of the claimed invention. Diagnostic assays are, typically, used to screen for those organisms that may be responsible for infection in an individual. For instance, Hammer, *et al.* (*Transplant Immunology* (1998) 6:235-241) discuss the importance of differentiating bacterial, fungal, and protozoal infections from viral infections before deciding on antibiotic therapy for transplant recipients. In addition, microbes causing infection in patients are often identified using differential growth media under typical culture conditions. SEQ ID NOs:1083 and 1095 would still have utility and usefulness to the skilled practitioner even if the claimed nucleotide sequences were not used to differentiate *Pseudomonas* or *Helicobactor* infections from *Chlamydia* infections. Using the claimed sequences to limit the scope of possible pathogens to two organisms would allow for the more rapid

identification of the pathogen responsible for infection in clinical settings (*e.g.*, such a preliminary indication of the infectious agent would reduce the time required, types of medium required, and amounts of media necessary to conclusively identify the organism). Furthermore, a number of diagnostic criteria are usually required before a definitive diagnosis is made. This point is illustrated in the case study of Ley, *et al.* (*Archives of Disease in Childhood* (1997) 77:148-149), in which an amplification reaction of the 16S gene is used to narrow the range of possible infective agents to a list of common meningitis pathogens, the size of the 16S product is compared to those of the suspected pathogens, the 16S product is sequenced, and an additional gene from the pathogen is amplified before making a definitive diagnosis. Accordingly, Applicants submit that the identified sequences have utility and reconsideration, and withdrawal of the rejection set forth under 35 U.S.C. § 101 is respectfully requested.

Claims 1-3, 8-16, 30, and 51-52 have been rejected under 35 U.S.C. § 112, first paragraph, because one skilled in the art would not know how to use the claimed subject matter because the claimed invention is not supported by a specific, substantial, and credible utility, or alternatively, a well-established utility. As indicated *supra*, it is respectfully submitted that the claimed polynucleotide sequences are useful in nucleic acid based assays for the detection of *C. trachomatis* in biological samples. As such, it is respectfully submitted that one skilled in the art would know how to use the claimed subject matter. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-3, 8-16, 30, 51-52, and 57-58 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the invention was filed, had possession of the claimed invention. Applicants respectfully traverse. As discussed in the interview of October 19, 2001, the entire genome of the organism has been sequenced and provided in SEQ ID NO:1. Accordingly, Applicants were in full possession of the nucleotide sequence, and, indeed, had described the same within the specification. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 1-3, 51, 52, 57, and 58 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Genbank accession number M74221. Applicants respectfully submit that the prior art applied in the Office Action does not anticipate the claimed sequences and fails to teach these same

polynucleotide sequences, nor does the prior art contain the requisite degree of homology to the claimed sequence. The prior art is 99.115% homologous to the claimed sequence whereas the claim recites 99.9% homology. Reconsideration and withdrawal of the rejections is respectfully requested.

Claims 1-3, 9-11, 13, 15, 51, 52, 57, and 58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Genbank sequence having accession number M74221. The Office Action states that it would have been obvious to one of skill in the art to link the Genbank sequence to regulatory elements, prepare transformed host cells containing the sequences in operatively linked vectors, and make complements of the sequences. It is well settled law that all the claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants respectfully submit that the Genbank sequence does not teach the claimed polynucleotide sequences nor does the Genbank sequence teach all the limitations found in the claims (for example, a sequence having 99.9% homology to the sequence of SEQ ID NO:1089). Withdrawal of this obviousness rejection is respectfully requested.

Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Genbank sequence M74221 in view of Southern *et al.* (U.S. Patent No. 5,436,327). The Office Action states that the Genbank sequence (M74221) describes nucleic acid sequences within the scope of the instant claim and Southern *et al.* teach the preparation and use of DNA chips. Applicants respectfully submit that the Genbank sequences do not constitute prior art applicable to the claims, and fail to teach each and every limitation of the claims (for example, 99.9% homology to the sequence of SEQ ID NO:1089). Southern *et al.* do not cure this defect in the primary reference. Accordingly, it is respectfully submitted that the rejection fails to raise a *prima facie* case of obviousness for claim 30. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks and the amendments to the claims, Applicants believe that the pending claims are now in condition for allowance, and such action is respectfully requested. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/jaj

Attachments: Certificate of Mailing by Express Mail
Request for Continued Examination (RCE) Transmittal (form PTO/SB/30) (in duplicate)
Copy of March 11, 2002 Declaration (regarding biological deposit)
Return Receipt Post Card